K081733

Boston Scientific

Endoscopy
100 Boston Scientific Way
Marlborough, MA 01752-1234
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510(K) SUMMARY

1. 510(k) Owner:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: (508) 683 – 4141
Fax: (508) 683 – 5939

Contact: Mr. Wing Ng
Title: Regulatory Specialist
Date Prepared: June 17, 2008

OCT 27 2008

2. Device:

Trade Name: WallFlex™ Biliary RX Stent System
Common Name: Biliary Stent System
Classification Name: Biliary Catheter and Accessories
Regulation Number: 21 CFR 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's currently marketed uncovered WallFlex Biliary RX Stent System (K061231).

4. Device Description:

The proposed 10mm X 40mm Uncovered WallFlex Biliary RX Stent System consists of a self-expanding 10mm outer diameter by 40mm length metal stent and a delivery catheter. The proposed stent features Platinum cored Nitinol wires wound together to form a cylinder with proximal and distal flares. The stent is mounted onto a sheath delivery system which is a coaxial tubing assembly. This tubing assembly constrains the stent onto the delivery catheter shaft until the stent is released by retracting the exterior tube.

5. Intended Use:

The WallFlex Biliary RX Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

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6. Technological Characteristics:

The proposed 10mm X 40mm Uncovered WallFlex™ Biliary RX Stent System has identical technological characteristics to the currently marketed uncovered WallFlex Biliary RX Stent System (K061231) with the exception of the stent outer diameter and the stent length dimensions. The purpose of this premarket notification is to add a new stent configuration of 10mm outer diameter by 40mm length that was previously not included in the matrix of cleared uncovered WallFlex Biliary RX Stent System (K061231) sizes.

7. Performance Data:

Performance testing was completed to establish substantial equivalence between the proposed device and the predicate device. This testing included dimensional evaluation, radial expansion force, radial compression force, trackability, deployment force, and reconstrainment force. The results of the performance testing show that the proposed device performed similarly to the predicate device which supports the determination of substantial equivalence.

8. Conclusion:

Based on performance testing results, Boston Scientific Corporation has concluded that the proposed 10mm X 40mm Uncovered WallFlex Biliary RX Stent System is substantially equivalent to the currently marketed uncovered WallFlex Biliary RX Stent System (K061231).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Wing Ng
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752-1234

OCT 2 7 2008

Re: K081733
Trade/Device Name: 10mm X 40mm Uncovered WallFlex™ Biliary RX Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: October 17, 2008
Received: October 20, 2008

Dear Mr. Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K081733

Device Name: 10mm X 40mm Uncovered WallFlex™ Biliary RX Stent System

FDA's Statement of the Indications for Use for device:

The WallFlex™ Biliary RX Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081733